

STUDY PROTOCOL

Functional Outcome Comparison of Implantless Bone-Patellar Tendon Autografts Using Press-Fit Fixation Technique and Hamstring Autografts Using Implant in Arthroscopic Anterior Cruciate Ligament Reconstruction: A Prospective Study

NCT number: not yet registered

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Study Protocol

Diagnosis of ACL rupture was done by physical examination using Lachman Test, Anterior Drawer Sign Test, and Pivot Test on both knee. Another test was also performed to exclude another knee ligament rupture, such as Posterior Drawer Test, Varus & Valgus Test. MRI was obtained to make an accurate diagnosis for ACL rupture using 3 projection, which were coronal, sagittal, and axial, each on T1 and T2 weighted image. After the diagnosis was confirmed, then the subject underwent a surgery performed by single same operator in Sports Injury Division of Orthopaedic Department in Gatot Soebroto Army Hospital.

Anterior cruciate ligament (ACL) reconstruction on the main treatment group was using press-fit graft fixation technique by Edgar Michael (Figure 1). After the subject was positioned in prone, area of surgery was draped with aseptic and antiseptic technique. A midline skin incision was made that extends from inferior pole of patella up to anterior tibial tuberosity. Patella tendon with tibial tuberosity bone block were harvested, patella bone was left intact. The tendon was fixed together with non-absorbable suture.

The knee was fully flexed. Femoral tunnel was drilled at 2 mm from posterior wall of lateral condyle on 1 o'clock and 11 o'clock. Bone plug were prepared into cone shape with the length equal to the femoral tunnel length. The diameter of the bone plug was 1 mm more than the femoral diameter to ensure press-fit mechanism. The ACL insertion at tibia was determined 8-10 mm in front of PCL insertion. The tunnel was made at an angle of 60 degrees to the distal direction.

Bone block were inserted into the femoral tunnel and the patella tendon was inserted into the tibia tunnel. Small hole was drilled by using a 2.0 K-wire at the distal opening of tibia tunnel. Fixation of the end of tendon graft was made into the hole by using polyester non-absorbable suture. Fixation was made by manual tensioning, double knots and posterior drawer position to ensure tight fixation. The wound was sutured layer by layer.



Figure 1. Schematic of the implantless press-fit ACL reconstruction

On the other hand, comparison treatment group in our study uses hamstring tendon graft for ACL reconstruction, fixed by endobutton implant for femoral fixation and bioscrew for tibial fixation.

Objective functional outcome is obtained by using a Rollimeter when doing a Lachman Test (Figure 2), performed at preoperation and 6 months postoperation. For subjective functional outcome, was obtained by IKDC Subjective Knee Evaluation Form (IKDC), Tegner Lysholm Knee Scoring Scale (Tegner) and Knee Injury and Osteoarthritis Outcome (KOOS). It was performed at preoperation, 1 month, 3 months and 6 months postoperation.



Figure 2. Rollimeter measurement

Statistical Analysis Plan

Statistical data was processed with SPSS ver. 18 (IBM). Statistical test using Pearson Chi Square or Exact Fisher Test for proportion data. Paired T-test or Mann-Whitney U/Wilcoxon *sum rank* and McNemar for continuous numeric data.